

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey et al**

Application No.: **10/694,183**

Filed: **October 28, 2003**

For: **Phosphodiesterase Inhibitors and Nitric Oxide Donors,  
Compositions and Methods of Use**

Docket No: 102258.287US4

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450



**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

A copy of each of the cited references is being submitted herewith. A copy of the cited U.S. patents and U.S. publications are not being submitted pursuant to 37 CFR § 1098(e).

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being submitted before the mailing date of a first office action on the merits or a notice of allowance. Accordingly, no fee is due.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,

Edward D. Grieff  
Registration No. 38,898

Date: December 15, 2003  
HALE AND DORR LLP  
1455 Pennsylvania Avenue, NW  
Washington, DC 20004  
Phone: (202) 942-8400

Please type a plus sign (+) inside this box

+

PTO/SB/08A (10-96)

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

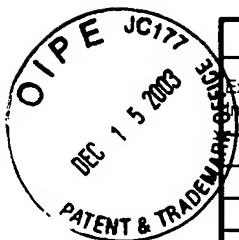
Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Sheet 1 of 6 Attorney Docket Number 102258.287 US4



## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,476,037	B1	Wallace	11-05-2002	
		6,133,272		Garvey et al	10-17-2000	
		6,172,060		Garvey et al	01-09-2001	
		6,172,068		Garvey et al	01-09-2001	
		6,177,428		Garvey et al	01-23-2001	
		6,197,782		Garvey et al	03-06-2001	
		6,197,778		Garvey et al	03-06-2001	
		6,211,179		Garvey et al	04-03-2001	
		6,211,881		Garvey et al	04-24-2001	
		6,232,321		Garvey et al	05-15-2001	
		6,316,457		Garvey et al	11-13-2001	
		6,462,044		Garvey et al	10-08-2002	
		6,331,543		Garvey et al	12-18-2001	
		5,958,926		Garvey et al	09-28-1999	
		RE37,234		Garvey et al	06-19-2001	
		5,874,437		Garvey et al	02-23-1999	
		5,767,160		Kaesemeyer	06-16-1998	
		5,891,459		Cooke et al	04-06-1999	
		5,919,474		Place et al	07-06-1999	
		6,071,272		Hoffman et al	06-06-2000	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	/	WO	98/19672		NitroMed, Inc.	05-14-1998		
	/	WO	98/58633		Queen's University	12-30-1998		
	/	WO	99/51252		Daily Wellness Co	10-14-1999		
	/	WO	00/00212		Nutracorp Sci.	01-06-2000		
	/	WO	00/15233		Zonagen, Inc.	03-23-2000		

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box

+

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

6

### Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

102258.287 US4

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Wallace et al, Anesth. Analg., 90:840-846 (2000).	
		Clarkson et al, J. Clin. Invest., 97(8):1989-1994 (1996).	
		Creager et al, J. Clin. Invest., 90:1248-1253 (1992).	
		Doherty, "Oral, Transdermal, and Transurethral Therapies for Erectile Dysfunction," Male Infertility and Dysfunction, Chapter 33, pages 452-467 Hellstrom, Ed., Springer Verlag, New York, NY	
		Egashira et al, Circulation, 94(2):130-134 (1996).	
		Golino et al, N. Engl. J. Med., 324(10):641-648 (1991).	
		Hasdai et al, Circulation, 96(10):3390-3395 (1997).	
		Moncada et al, Biochem. Soc. Trans., 17:642-644 (1989).	
		Moncada et al, Biochemical Pharmacology, 38(11):1709-1715 (1989).	
		Nakanishi et al, Am. J. Physiol., 263 (6 Pt. 2):H1650-H1658 (1992).	
		Palmer et al, Biochem. Biophys. Res. Commun., 153:1251-1256 (1988).	

Examiner  
Signature

Date

Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box

+

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

4

of

6

### Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

102258.287 US4

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Richard et al, Am. J. Physiol., 259:H1433-H1439 (1990).	
		Ueno et al, J. Cardiovascular Pharmacology, 26(Supp. 4):S13-S20 (1995).	
		Vallance et al, Lancet, 2:997-1000 (1989).	
		Wallace et al, Anesthesiology, 90:1577-1586 (1999).	
		Ballard, J. Urology, 159(6):2164-2171 (1998).	
		Bellamy et al, Cardiovasc. Res., 40(2):410-417 (1998).	
		Bossaller, Basic Res. Cardiol., 82(4):396-404 (1987).	
		Ceremuzynski et al, Am. J. Cardiol., 80(3):331-333 (1997).	
		Chester et al, Lancet, 336(8720):897-900 (1990).	
		Drexler et al, Lancet, 338:1546-1550 (1991).	
		Furchgott et al, Blood Vessels, 24(3):145-149 (1987).	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box



PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

5

of

6

### Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

102258.287 US4



### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Hiramatsu et al, Ann. Thorac. Surg., 60(5):1187-1192 (1995).	
		Jackson et al, Am. J. Cardiol., 83(5A):13C-20C (1999).	
		Klein et al, Eur. Heart J., 16(5):603-609 (1995).	
		Kobayashi et al, Coron. Artery Dis., 10(5):321-326 (1999).	
		Koifman et al, J. Am. Coll. Cardiol., 26(5):1251-1256 (1995).	
		Pearson, Ann. Thorac. Surg., 51(5):788-793 (1991).	
		Polson, Annual Review Pharmacol., 26(Suppl. 4):S13-S20 (1996).	
		Simonetti et al, "Biphasic effect of nitroglycerin on coronary hemodynamics in normal subjects," Z. Kardiol., 78(Suppl. 2):52-55; discussion 64-67 (1989).	
		Vallance et al, Cardiovasc. Res., 23:1053-1057 (1989).	
		Vallance et al, Biomed. Pharmacother., 43:113-119 (1989).	
		Webb et al, Am. J. Cardiol., 83(5A):21C-28C (1999).	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.